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March 30, 2021

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter as a supplement to the Plaintiffs' March 23, 2021 letter, to update the Court on further developments since the submission of the letter last week, in advance of the March 31, 2021 Discovery Hearing and Case Management Conference.

1. **Defense Request for Dismissal of Louisiana Plaintiffs' Claims**

The Parties met and conferred on March 29, 2021 regarding Defendants' contention that all Louisiana Plaintiffs' claims were dismissed with prejudice pursuant to this Court's Orders on the Motions to Dismiss on the Master Complaints. Defendants consequently suggest that the Bellwether pool should be repopulated with non-Louisiana plaintiffs. Plaintiffs disagree and

informed Defendants during the meet and confer that the Court's Orders on the Motions to Dismiss only dismissed claims not cognizable under the Louisiana PLA and certainly did not constitute a decision dismissing all of the individual plaintiffs' claims that remain viable, whether as pleaded or pursuant to amendment of the pleadings - the legal standard for asserting claims under the Louisiana Product Liability Act does not require a plaintiff to cite to the Act by name for a Complaint to be sufficient, but Plaintiffs intend to amend to add references to the PLA for maximum clarity. Notably, one defense lead counsel took the position that the issue must be resolved before the bellwether process can proceed further, and another took the position that the cases should be removed from the bellwether pool while the Court addresses the issue - demonstrating that this argument is actually an effort to substantially re-form the bellwether pool.

Defendants' overreaching position does not square with how Louisiana courts have addressed this exact issue. In *Lewis v. GE Healthcare, Inc.*, the Western District of Louisiana addressed this very issue approximately one year ago. In ruling on the defendant's assertion that the plaintiff's claims should be dismissed for failing to cite to the Louisiana Product Liability Act ("LPLA"), the court held that this is an inappropriate application of the law:

> GEHC contends that these claims fail because Lewis did not explicitly assert a claim under the LPLA. It is manifest, however, that a complaint need not "correctly specify the legal theory giving rise to the claim for relief." Further, "[c]ourts must focus on the substance of the relief sought and the allegations pleaded, not on the label used." Gearlds, supra. Because failure to warn, breach of express warranty, and unreasonably dangerous design are cognizable under the LPLA, the Court will proceed to determine whether Lewis alleged sufficient facts to support these claims.

Lewis v. GE Healthcare, Inc., No. 5:19-CV-00490, 2020 WL 1490719, at *4 (W.D. La. Mar. 25, 2020) (internal citations omitted); *see also King v. Bayer Pharm. Corp.*, No. CIV.A. 09-0465, 2009

WL 2135223, at *5 (W.D. La. July 13, 2009) ("Clearly, Plaintiffs' complaint contains the requisite factual allegations to state a claim under the LPLA. Moreover, the factual allegations support claims under the LPLA, even though Plaintiffs' complaint used titles for their claims that fell outside the LPLA.").

Similarly here, Plaintiffs' first Master Complaints were found to have sufficiently pleaded causes of action, and in many cases, Defendants chose not to challenge the sufficiency of those pleadings. The only issue that remains is whether the Louisiana Product Liability Act recognizes statutory causes of action under the facts pled in Plaintiffs' Master Complaints. It does. Thus, the pleadings already are sufficient under the Louisiana PLA, and the Court has recognized that those claims are viable. The proposed amendments will further clarify this.

"The manufacturer of a product shall be liable to a claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity." La. Rev. Stat. Ann. § 9:2800.54(A). As the Fifth Circuit explained,

> To maintain a successful products liability action under the LPLA, a plaintiff must establish four elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else.

Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 260–61 (5th Cir. 2002). Defendants did not contend in their Motions to Dismiss that these elements were not pled, and nor could they.

For this reason, Plaintiffs oppose Defendants' effort to obtain a dismissal of Plaintiffs' viable claims under the Louisiana PLA, and the removal of all Louisiana Bellwether cases selected by the parties from the bellwether pool.

Likewise, in their recent letter to the Court, Defendants referenced the New Jersey Consumer Fraud Act claims in the Master PI Complaint, which the Court ruled were subsumed as currently pled. In accordance with the Court's grant to file a motion for leave to amend the Master PI Complaint, Plaintiffs intend to address the pleading deficiencies the Court found regarding these claims.

2. Hetero Discovery Status

Plaintiffs write to update the Court as the status of discovery issues with Hetero since the letter of last week. In the intervening week since the last discovery conference, Hetero has continued to produce documents. However, that piecemeal production has not fully resolved any of the issues raised in Plaintiffs' letter of last week.

Hetero is still missing key versions of numerous quality system manuals, SOPs, site master files, Master SOP indexes, and testing documents, despite multiple supplemental productions to date.

Hetero still has not produced documents related to the drafting, editing, modification, distribution, and implementation of any of the quality systems manuals, testing documents, and SOPs Hetero has produced. It is clear that these manuals, SOPs, and other documents were not created, edited, and modified in a vacuum, there had to be versions circulated, edits, redlines, comments, etc. It is also clear that these manuals, SOPs, and other documents had to have been

distributed and implemented. Yet, Hetero has not produced documents related to any such creation, editing, modification, distribution, or implementation.

Hetero still has not produced a list of the applications, databases, sharepoints, and other central document and data locations that contained the relevant documents and data, despite its agreement to do so weeks ago.

Just this morning, Hetero produced what it identified as batch records and certificates of analysis, which are categories of documents that should have been produced months ago. Plaintiffs are in the process of loading these documents and have not had a chance to review them, but on their surface, given the number of documents produced, it appears unlikely that this is a complete production.

Much more importantly, as Plaintiffs review the documents Hetero has now produced, we are finding evidence of more documents that are clearly relevant, and clearly missing. For example, as Plaintiffs have now discovered, Hetero was supposed to have conducted internal audits either every three months or every year, depending on the specific audit, and that presentations were made with regard to internal audits. However, Plaintiffs have only been able to locate a total of three internal audits, and no presentations concerning audits. These are documents that are clearly responsive to Plaintiffs' document requests, yet Plaintiffs are only discovering even their existence now as a result of Hetero's production. This pattern of Hetero failing to produce responsive documents, or even entire categories of responsive documents, unless specifically found as missing and identified to Hetero by Plaintiffs has been playing out for months now. This is of enormous concern as it is certain that Plaintiffs are incapable of identifying all missing documents due to the fact that they do not know the full extent of what exists. It is not Plaintiffs' responsibility to

specifically identify individual responsive documents, it is Hetero's responsibility to properly and fully respond to Plaintiffs' document requests. Hetero clearly has not done so.

Finally, it also now appears that some custodians and witnesses were never issued litigation holds, including Venkata Pravin Kumar Penubaka, Panchakshari Nanyappa Gowda; Dr. B.V. Ramireddy, Yogeswar Reddy Mamilla, Mohan Reddy Chilukurri, Bandaru Venkata Ramarao ("B.V. Ramarao"), and Dr. Murali Nagabelli, all of whom are expected deponents.

Hetero's production continues to be deficient and has significantly prejudiced Plaintiffs' ability to proceed with depositions related to Hetero, which have now been postponed multiple times.

3. Aurobindo Discovery Deficiencies

A. Unsearched Sources of Data

Since the conference last week, Aurobindo has produced a total of 46 documents. This is in spite of repeated assurances from Aurobindo that it has been working hard to produce documents on time and on a rolling basis. While the Court initially had required Aurobindo to produce documents on or before March 12, 2021 per Plaintiffs' agenda letter (ECF No. 967, pp.9-10), Plaintiffs indicated in a previous agenda letter they were willing to grant Aurobindo an extension to finish its production on or before April 9, 2021. (ECF No. 1011, pp. 20-21).

Suffice it to say, Aurobindo has not been producing large volumes of documents, and there are approximately 14 custodial files (or 15 if the Court approves Plaintiffs' pending request to receive Dr. Rao's file) that have not been produced, as well as potentially tens or hundreds of thousands of responsive noncustodial documents.

To the extent this is not clear from prior transcripts, Plaintiffs expect that all documents from Aurobindo remain due on April 9, 2021 and request that the Court confirm this to be the case.

B. Aurobindo's Hard Drives

Plaintiffs understand this data has now been received by Aurobindo's vendor and ask that all of these documents be produced in accordance with the April 9, 2021 deadline mentioned above.

C. Aurobindo Purchases from ZHP

The parties met and conferred on this issue on Monday, March 29, 2021. Aurobindo has not yet agreed to produce documents related to these purchases, and Plaintiffs hope Aurobindo will confirm that it will produce documents related to this issue.

D. Missing Standard Operating Procedures

The parties met and conferred on this issue on Monday, March 29, 2021. Aurobindo has agreed to produce the vast majority of the policies and procedures, and this issue appears to be resolved, pending Aurobindo responding to Plaintiffs as to a few remaining issues.

II. Privilege Log Challenges

Plaintiffs met and conferred on Aurobindo's privilege log, and while Aurobindo has agreed to de-designate some documents, the same categories of disputes remain.

III. Improperly Withheld Documents

Aurobindo has agreed to produce nearly all of these documents after a meet and confer, and Court intervention is no longer needed.

IV. Additional Issues

A. Aurobindo's Failure to Preserve Relevant Evidence

Plaintiffs have now completed two depositions of fact witnesses from AuroLife USA, Bhadresh Doshi and Prasad Gorijavolu. [redacted]

(Ex. A hereto).[1]

[redacted]

(Ex. B hereto).[2] After these depositions, Plaintiffs requested that Aurobindo update its litigation hold letter. Ms. Heinz provided the attached letter, which showed that (1) [redacted], in spite of the fact that new custodians (*See* ECF 1011, p. 20) were approved by the Court during the mid-March case management conference; (2) [redacted]. (Ex. C hereto).[3]

"Spoliation is generally defined within the applicable jurisprudence as the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence

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[1] In accordance with the Confidentiality and Protective Order, Plaintiffs will not attach this document to the version of this letter filed on ECF. Instead, Plaintiffs will email it to the Court for its review with an unredacted version of this letter.

[2] In accordance with the Confidentiality and Protective Order, Plaintiffs will not attach this document to the version of this letter filed on ECF. Instead, Plaintiffs will email it to the Court for its review with an unredacted version of this letter.

[3] Aurobindo inexplicably marked this letter "Restricted Confidential," but it does not meet the definition of that term in the Confidentiality and Protective Order, and Aurobindo did not respond to Plaintiffs' request to de-designate the document. As a result, Plaintiffs will not file this document on ECF but will email it to the Court with the unredacted copy of this letter.

in pending or reasonably foreseeable litigation." *In re Actos (Pioglitazone) Prod. Liab. Litig.*, No. 6:11-MD-2299, 2014 WL 2872299, at *1 (W.D. La. June 23, 2014) (internal cites omitted) (citing *Zubulake v. UBS Warburg, LLC,* 229 F.R.D. 422, 430 (S.D.N.Y.2004) and *West v. Goodyear Tire & Rubber Co.,* 167 F.3d 776, 779 (2nd Cir.1999)).

Based upon the information provided by Aurobindo's counsel and on the testimony from its witnesses, Aurobindo failed to preserve evidence. Plaintiffs therefore are requesting that Aurobindo produce the following for the period of 2014 to the Present:

(1) All document retention policies, whether in the form of a Standard Operating Procedure or in any other form
(2) Document preservation policies and practices, whether in the form of a Standard Operating Procedure or in any other form
(3) Document or data deletion policies, whether in the form of a Standard Operating Procedure or in any other form
(4) Copies of the litigation holds sent to all recipients in Ms. Heinz's attached letter
(5) A 30(b)(6) deposition of a company witness who can testify to the following general topics, with a more formalized notice to follow, pending Court approval:
    a. Categories (1)-(4) and the company's adherence to those policies
    b. The location and existence of custodial and noncustodial data responsive to Plaintiffs' Rule 34 Requests
    c. The company's implementation of litigation holds

Plaintiffs reserve the right to add to or refine these topics at a later date but are seeking Court approval to move forward with the notice and deposition process.

Plaintiffs further request that after the April 9, 2021 production deadline, the Court set an evidentiary hearing on the documents that exist, compared to those that were produced to Plaintiffs and that the Court rule on whether Plaintiffs have suffered prejudice as a result of Aurobindo's failure to produce and preserve documents.

4. Mylan Discovery Deficiencies

A. Withheld Non-Responsive Documents

Approximately four (4) weeks ago, Plaintiffs challenged in excess of 4,000 documents Mylan had withheld as non-responsive. The documents challenged by Plaintiffs were part production of some 35,000 documents, of which a staggering 20,000 were produced merely as slip sheets that stated "withheld – non-responsive/other product(s)." In an attempt to meet Mylan in the middle, Plaintiffs proceeded to expend time and resources to quickly triage the issue, and identified a smaller universe of the larger 20,000 withheld documents by using only the limited information available to them (metadata and the context of the other documents within the same families). This is how Plaintiffs arrived at their smaller list of 4,000 documents at issue before the Court right now.

The above is a process that has had to be repeated time and time again with Mylan throughout Mylan's productions of documents. As Plaintiffs prepare for depositions, Plaintiffs continually notice that there are attachments that have been withheld on the basis of responsiveness that should have been produced in the primary instance. Plaintiffs are required to make an affirmative request for such documents. Mylan invariably proceeds to produce such documents after the request has been made, although in a delayed manner. It should not be surprising that Plaintiffs are continually discovering instances of withheld attachments as they proceed to conduct deeper document review as Mylan's entire production of 283,525 documents consists of nearly 100,000 documents that are "withheld – Non-responsive/other products."

In the intervening time between when Plaintiffs initially made their most recent challenge to certain documents withheld as "non-responsive" and tomorrow's Case Management

Conference, Plaintiffs will have taken nearly 21 hours of Rule 30(b)(6) testimony from Mylan corporate designees on some of the most important Rule 30(b)(6) topics pertaining to Plaintiffs' case against Mylan, including risk evaluations of recovered solvents, cGMP compliance, SOPs, nitrosamine and other testing results, etc. In the meantime, Mylan refused to produce any of the documents identified by Plaintiffs, requiring Plaintiffs to raise their responsiveness to the Court. At the last hearing, the Court ordered Mylan by Monday 3/29 to submit a letter explaining the non-responsiveness of twelve (12) documents identified by Plaintiffs in their submission to the Court, and to also submit approximately 350 documents to the Court as part of the random sampling procedure the Court proposed. As Plaintiffs advised the Court in a separate communication, the Court did not receive a letter from Mylan regarding the 12 documents as ordered. That is because Mylan withdrew its non-responsiveness determinations as to all 12 of those documents without ever notifying the Court.

Just like the remaining 4000 documents (and probably thousands more documents), those 12 documents should have been produced and available to Plaintiffs' counsel during the 21 hours of deposition testimony already taken on topics to which the documents directly relate (for example, nitrosamine testing results appear to be among the documents and Plaintiffs have already questioned for 2 days Mylan's witness designated on testing results).

To the extent the Court orders Mylan to produce some or all of the 4000 documents, Plaintiffs expressly reserve all rights regarding seeking additional deposition time with certain witnesses and/or further appropriate relief associated with the remainder of the withheld documents in Mylan's productions.

B. Unit 7

Finally, Plaintiffs reiterate their limited request for certain documents pertaining to the FDA's inspection of Mylan's Unit 7 facility. The FDA's Unit 7 inspection and observations are plainly quite relevant as dealing with the same vendor(s) and Mylan's inadequate vendor approval procedures, the same recovered solvent and Mylan's failure to test it for impurities (a failure that also occurred at Unit 8), and Mylan's own referral of the FDA to Mylan's Unit 8 corrective actions taken at Unit 7 that make these documents even more relevant than they already were. For further arguments regarding the responsiveness of these documents, Plaintiffs largely refer the Court back to the previous hearing's transcript.

Plaintiffs have considered the Court's stated "slippery slope" concerns, but wish to emphasize to the Court that 1) Plaintiffs' request for documents is limited to the inspection reports and exhibits, Mylan's responses and exhibits, and any FDA correspondence and meeting minutes (no search terms being requested), and 2) Your Honor may always set limits or outright deny Plaintiffs' future requests, if any, for additional documents. Such a concern should not preclude Plaintiffs from access to these narrowly-tailored and highly relevant documents.

Respectfully,

ADAM M. SLATER